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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/644,252	08/20/2003	Thomas Zdeblick	4002-3378/PC242.38	6078
52196	7590	04/05/2006	EXAMINER	
KRIEG DEVAULT LLP ONE INDIANA SQUARE, SUITE 2800 INDIANAPOLIS, IN 46204-2709			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 04/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/644,252

Applicant(s)

ZDEBLICK ET AL.

Examiner

Julian W. Woo

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 19-25 and 27-50 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19-25, 27, 30-46, 49 and 50 is/are rejected.
- 7) ☒ Claim(s) 28, 29, 47, and 48 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 27, 38-40, 44-46, 49, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Reuther et al. (4,324,550). Reuther et al. disclose, at least in the figures and in col. 1, lines 41-51, a fusion device comprising a solid, elongate body (1), external threads (4) extending substantially entirely along the length of the body, a hollow interior (7), at least one opening in communication with the interior (8) where the threads are circumferentially interrupted by a pair of oppositely disposed truncated walls (5 and/or 6) to define a pair of threaded arcuate side walls that are tapered along a substantial portion of the length of the body, where the body is formed of a porous biocompatible material (e.g., aluminum-oxide ceramic or carbon-fibers reinforced polyethylene) for permitting bone tissue ingrowth. Note: The introductory statement of intended use (“for facilitating arthrodesis in a disc space between adjacent vertebrae”) has been carefully considered but deemed not to impose any structural limitations on the claims patentably distinguishable over the device of Reuther et al., which is capable of being used as claimed if one desires to do so.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 19-25, 30, 31, and 34-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Brien (5,435,723) in view of Kaplan (5,282,861). O'Brien discloses the invention substantially as claimed. O'Brien discloses, at least in figures 1 and 2 and in col. 3, lines 25-45, a fusion device having a solid, elongate body (3), external threads (5) extending substantially entirely along the length of the body, a hollow interior (19, 20) and outer walls that are substantially continuously tapered along the length of the body, where the body is formed of a biocompatible material. However, O'Brien does not disclose that the material is a porous, open-celled substrate of a carbonaceous material or carbon foam with an infiltration of a group VB metal or tantalum. Kaplan teaches, at least in col. 3, line 19 to col. 4, line 46, a material for dental and orthopedic implants that

Art Unit: 3731

comprises a porous, open-celled substrate of a carbonaceous material or carbon foam with an infiltration of a group VB metal or tantalum. It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the material as taught by Kaplan in the device of O'Brien. Such a material would allow a strong, stable structure that mimics the microstructure of cancellous bone, acts as a matrix for the ingrowth of bone, and provides a porosity and surface area for encouraging new bone ingrowth.

4. Claims 32 and 33 rejected under 35 U.S.C. 102(b) as anticipated by Taylor (3,979,848) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Taylor in view of Gordon (4,186,486). Under 35 U.S.C. 102(b): Taylor discloses, at least in figures 5-7 and in col. 10, lines 52-64, a fusion device with an elongate body (124) and a hollow interior (134), and at least one opening in an outer wall in communication with the hollow interior, where the body includes an outer wall that is substantially continuously tapered along the length of the body, where the body is formed of a porous (via openings 136) biocompatible material and includes a bone growth inducing material within its hollow interior (blood). Alternatively and arguably, Taylor does not disclose porous biocompatible material as claimed. However, Gordon teaches, at least in figures 1-3 and in col. 1 line 33 to col. 2 line 55, a fusion device made of a porous, biocompatible material (e.g., polyethylene). It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Gordon, to make the device of Taylor out of a material such as polyethylene. Such a material would

Art Unit: 3731

provide a bone growth stimulating biochemical matrix that can be easily shaped to fit a surgical site.

5. Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Reuther et al. (4,324,550) in view of Kaplan (5,282,861). Reuther et al. discloses the invention substantially as claimed. Reuther et al. disclose, in col. 2, lines 12-19, a fusion device that can be made of various "materials employed in the human medicine." However, Reuther et al. do not disclose that the material is a porous, open-celled substrate of a carbonaceous material or carbon foam with an infiltration of a group VB metal or tantalum. Kaplan teaches, at least in col. 3, line 19 to col. 4, line 46, a material for dental and orthopedic implants that comprises a porous, open-celled substrate of a carbonaceous material or carbon foam with an infiltration of a group VB metal or tantalum. It would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the material as taught by Kaplan in the device of Reuther et al. Such a material would allow a strong, stable structure that mimics the microstructure of cancellous bone, acts as a matrix for the ingrowth of bone, and provides a porosity and surface area for encouraging new bone ingrowth.

***Allowable Subject Matter***

6. Claims 28, 29, 47, and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 3731

7. The following is a statement of reasons for the indication of allowable subject matter: None of the prior art of record, alone or in combination, discloses a fusion device including, inter alia, an elongate body, a hollow interior, and a pair of oppositely disposed arcuate side walls defining external threads, where the body is tapered substantially entirely along the length of the body, where the body is formed of a porous biocompatible material, where bone growth inducing material is disposed in the interior, and where the side walls have at least one opening.

8. As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

#### ***Response to Amendment***

9. Applicant's arguments with respect to claims 26, 28-30, 38-44, and 44-49 have been considered but are moot in view of the new ground(s) of rejection.

#### ***Conclusion***

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Sneer (3,955,280), Heimke et al. (4,185,383), Hakamatsuka et al. (4,713,006), and Kownacki et al. (5,816,812) teach fusion devices.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

Art Unit: 3731

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo  
Primary Examiner

April 1, 2006